EXHIBIT 2

From:	Chris J. Tardio
Sent:	Friday, March 06, 2015 3:07 PM
To:	lauren.dipaola@fda.hhs.gov
Cc:	Gerard Stranch (gerards@bsjfirm.com); 'Ben Gastel' (beng@bsjfirm.com) (beng@bsjfirm.com); Chalos, Mark P. (mchalos@lchb.com) (mchalos@lchb.com); Rehnquist, James C (JRehnquist@goodwinprocter.com); Puig, Yvonne K. (yvonne.puig@nortonrosefulbright.com); Schramek, Adam T. (adam.schramek@nortonrosefulbright.com); Hoffman, Eric (eric.hoffman@nortonrosefulbright.com); Parks Chastain (PChastain@bkblaw.com); C. J. Gideon; Matt H. Cline; Jeremy C. Cain
Subject:	FDA 30(b)(6) Notice of Deposition
Attachments:	Subpoena Package to Ms. DiPaolo (cover ltr, subpoena, 30(b)(6) NoD, Depo Protocol 3-6-15.pdf

Ms. DiPaola:

You have been speaking with Jeremy Cain in our office regarding arranging a deposition of the Food and Drug Administration in *MDL 2419*: *In re New England Compounding Pharmacy, Inc. Products Liability Litigation*.

Attached are:

1. Subpoena for the deposition
2. Notice of Deposition to the FDA pursuant Federal Rule of Civil Procedure 30(b)(6) and accompanying *duces tecum*
3. Deposition Protocol in this MDL.

You told Jeremy in past conversations that service on you would be sufficient to effectuate service on the FDA. We tried to call you several times this week to confirm that you would simply accept the notice, but we have not connected with you. So, we have had the subpoena issued. We have mailed the subpoena to your address, along with a copy of the Notice of Deposition and Deposition Protocol. Please let me know immediately whether you contest the service of the subpoena.. If the FDA contests that the mailing of the subpoena and notice constitute proper service, we will have it served in person on whomever you designate to accept service. Hopefully, that will not be necessary, consistent with past conversations with you.

The deposition is set for May 4, 2015, at 9:00 am CT, in our office in Nashville. This is a date during a week that the primary involved lawyers in these cases have set aside for depositions of "national" deponents in these cases. If we need to accommodate someone's schedule for the deposition, we will discuss. At this point, as discussed, we wanted to have the subpoena issued for a date that the lawyers have held in this case and provide you with sufficient time to designate the proper persons.

The attached Deposition Protocol governs the conduct of depositions in this litigation. Section I(f) deals with 30(b)(c) depositions. We are required to serve it on any deponents.

We are happy to discuss the best way to tender the witness fee and any mileage reimbursement once you let us know who will be testifying on behalf of the FDA. Once we know whom and where to have the check sent, we will promptly send it.

Lastly, I have copied the primary involved attorneys in the MDL cases pending in Tennessee. I have also filed this Subpoena, Notice of Deposition, and *duces tecum* in the main MDL docket. By doing so, all parties involved in the MDL (not just those involved in cases from Tennessee) will be given notice of this deposition.

Again, if you believe that the service of this subpoena and Notice consistent with the conversations we have had with you is deficient in any way, please let me know immediately.

After you have had a chance to review the Notice and accompanying documents, please feel free to call Mr. Cain or me.

Thanks.

Chris J. Tardio, Esq.
Member // Gideon, Cooper & Essary, PLC
315 Deaderick Street
Suite 1100
Nashville, Tennessee 37238
(615) 254-0400 (phone)
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J. BLAKE CARTER[1]
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MATT H. CLINE
MATTHEW J. NATHANSON
JEREMY C. CAIN

[1]LICENSED IN TN & FL
[2]LICENSED IN TN, AL & TX
[3]LICENSED IN TN & GA
[4]LICENSED IN TN & KY
[5]LICENSED IN TN & WI
[6]LICENSED IN TN & KS

March 6, 2015

Via US Mail and Electronic Mail
Lauren DiPaolo
Testimony Specialist
US Food and Drug Administration
Office of Enforcement
Division of Compliance Policy
12420 Parklawn Drive
Rockville, MD 20857

Re: MDL 2419: *In re New England Compounding Pharmacy, Inc. Products Liability Litigation II* Notice for FDA Deposition

Dear Ms. DiPaolo:

Consistent with your conversations with Jeremy Cain in our office, please find enclosed a notice of deposition and subpoena to testify, served pursuant Federal Rules of Civil Procedure 30(b)(6) and 45, respectively, for the Food and Drug Administration.

Please note that a *duces tecum* accompanies the Notice, requesting certain documents be produced. The deposition is set for May 4, 2015, at 9:00 am, at our office in Nashville. This is a date that the primary involved parties agreed to reserve for depositions in this litigation. Also enclosed is a copy of the Deposition Protocol governing the conduct of depositions in this litigation. A copy of this Notice and subpoena are being filed in the main docket for this litigation, providing notice to all parties in the MDL that this deposition shall be taken.

I invite you, if you wish, to call Mr. Cain or me after you have had a chance to review the Notice and speak with the appropriate persons.

Lastly, if you believe that the service of this Notice and subpoena is deficient in any way, please let me know immediately.

Thank you.

Very truly yours,

Chris J. Tardio

Enc: Subpoena to Testify at Deposition
30(b)(6) Notice + *duces tecum*
Deposition Protocol

cc: Gerard Stranch (via email)
Ben Gastel (via email)
Mark Chalos (via email)
James Rehnquist (via email)
Yvonne Puig (via email)
Adam Schramek (via email)
Eric Hoffman (via email)
Parks Chastain (via email)
C.J. Gideon (via email)
Matt Cline (via email)
Jeremy Cain (via email)

AO 88A (Rev. 02/14) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

In Re: New England Compounding Pharmacy, Inc. Products Liability Litigation
Plaintiff

v.

Tennessee Clinic Defendants
Defendant

Civil Action No. 1:13-md-02419

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: United States Food and Drug Administration (FDA)

(Name of person to whom this subpoena is directed)

☑ *Testimony:* **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

Place:	Date and Time:
Gideon, Cooper & Essary, PLC 315 Deaderick Street, Suite 1100 Nashville, TN 37238	05/04/2015 9:00 am CDT

The deposition will be recorded by this method: Stenographical means and by video

☑ *Production:* You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material: See attached Duces Tecum, Exhibit 1 to Notice of 30(b)(6) Deposition

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 03/05/2015

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Tennessee Clinic Defendants, who issues or requests this subpoena, are:

Chris J. Tardio; 315 Deaderick St., Suite 1100, Nashville, TN 37238; chris@gideoncooper.com; (615) 254-0400

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 1:13-md-02419

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____

on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named individual as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	**MDL No. 2419**
	)	**Dkt. No 1:13-md-2419 (RWZ)**
THIS DOCUMENT RELATES TO:	)	
All cases	)	

Notice of 30(b)(6) Deposition

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants"), pursuant to Federal Rule of Civil Procedure 30(b)(6), come now and give notice that the oral and videotaped deposition of the United States Food and Drug Administration ("FDA"), as an organization, will be taken on the topics detailed below. The FDA shall identify the person(s) who will speak on its behalf on each topic at least seven (7) days before the deposition(s).

The deposition will be taken on May 4, 2015, beginning at 9:00 a.m. (CDT) and continuing until completed. The deposition will take place at the offices of Gideon, Cooper & Essary, PLC, 315 Deaderick St., #1100, Nashville, TN 37238. The deposition will be recorded by stenographical means and by video.

Pursuant to Federal Rule of Civil Procedure 30(b)(6), the FDA's designee(s) shall be prepared to testify regarding the following subjects:

FDA's authority to investigate, inspect, regulate, and take action against NECC

1. The FDA's authority to investigate, inspect, regulate, and take enforcement action against NECC from 2002 through the meningitis outbreak, particularly in light of the information FDA learned about NECC's operations beginning in 2002.

2. The FDA's application of Compliance Policy Guide § 460.200 (2002) when making the decision whether to regulate compounding pharmacies like NECC (*i.e.*, compounding pharmacies with large-scale operations similar to conventional drug manufacturers), both before the meningitis outbreak and since the meningitis outbreak.

3. The FDA's internal policies (written or otherwise), procedures (written or otherwise), and training of staff from 2002 to the time of the meningitis outbreak on the (1) inspection of compounding pharmacies, (2) when regulatory action was appropriate against compounding pharmacies, and (3) distinguishing between traditional compounding, large-scale compounding similar to drug manufacturing (now called "outsourcing facilities"), and conventional drug manufacturers.

4. Generally, FDA's authority to take enforcement actions against drug manufacturers, and how that authority can be exercised (*i.e.*, generally, the differences between the types of enforcement actions available to the FDA, *e.g.*, private censures, warning letters, seizures, injunctions, criminal actions, civil penalties, *etc.*).

5. The decision by FDA to, following the meningitis outbreak, inspect and take action against 30+ compounding pharmacies.

FDA's investigation, inspections, regulation, and actions related to NECC

6. All complaints about NECC known by the FDA prior to the meningitis outbreak and the FDA's response to these complaints, including the internal decision-making regarding whether and how to investigate, inspect, and take action against NECC. The complaints and related investigations, inspections, and actions that the witness should be prepared to testify regarding include, but are not limited to:

a. Investigation in March 2002 and subsequent inspection on April 16, 2002 (and related 483)

b. Investigation in October 2002 and subsequent inspection (483 issued February 10, 2003)

c. 2002-03 internal meetings at FDA related to FDA's role in regulating NECC, as described in the February 24, 2003, FDA internal memorandum

d. The inspection request to the Investigations Branch of the New England District Office of the FDA dated June 2, 2004

e. The investigation and inspection conducted in September 2004 related to NECC production of trypan blue

f. Complaints about NECC in January and February 2006[1]

g. The 2006 Warning Letter issued to NECC (including the findings underlying the letter)

h. June 2007 MedWatch reports to FDA about NECC related to re-packaging of Avastin

i. June 2008 complaints to the FDA related to NECC betamethasone

j. September 16, 2008, FDA assignment for inspection of NECC, and the failure to do the inspection[2]

[1] One complaint emanated from Texas. One appears to have originated from within the FDA.
[2] This includes actions in February 2009 and September 2009 documented in internal emails and memoranda indicating FDA's plan to (re-)inspect NECC and take immediate action (which, apparently, did not occur).

k. October 31, 2008, letter to NECC asserting that FDA has the authority to take action and that FDA will re-inspect NECC

l. Reports from anonymous informants in October 2009 and July 2010 about Ameridose and its leadership (leadership shared with NECC) forging sterility documents and knowingly not following proper sterility procedures

m. 2011 reports from the Colorado Board of Pharmacy and the FDA's failure to act against NECC based on these reports.

7. Any and all complaints about NECC made to the FDA or actions by the FDA in response to complaints about NECC not specifically referenced in Number 6(a)-(m).

8. Any and all correspondence and communications between the FDA and NECC (including its owners, agents, employees, and representatives) not specifically referenced in Number 6(a)-(m).

9. Any and all correspondence and communications between the FDA and state pharmacy boards related to NECC not referenced in Number 6(a)-(m).

10. Whether, (1) based on information learned by the FDA about NECC prior to the meningitis outbreak and (2) considering the statutory factors set out in 503A and the factors set out in the 2002 CPG, NECC was operating like a conventional drug manufacturer (or, at a minimum, operating on a scale not akin to a traditional compounder), subjecting it to FDA regulatory authority.

11. The FDA's authority prior to the meningitis outbreak to share the information FDA had about NECC with the State of Massachusetts and recommend to the State that it take enforcement action against NECC's state license.

State of Massachusetts

12. The FDA's cooperation with the State of Massachusetts in investigating, inspecting, and taking action against NECC prior to the meningitis outbreak.

13. Whether the FDA believes it was the State of Massachusetts' responsibility to take enforcement action against NECC given the information known by the FDA and the State of Massachusetts about NECC prior to the meningitis outbreak.

The information known by the FDA about NECC and whether/how it was made public

14. What, if any, of the information known by the FDA about NECC's failure to follow federal law, state law, or industry standards for production of drugs was made publicly available prior to the meningitis outbreak and the steps necessary for potential customers of NECC to obtain the information from the FDA.

15. What information known by the FDA about NECC's failure to follow federal law, state law, or industry standards for production of drugs was available to potential customers of NECC had they requested such information from the FDA prior to the meningitis outbreak.

16. Whether the FDA issued any alerts to health care providers prior to the meningitis outbreaks related to NECC (*e.g.*, that it was unsafe to purchase from NECC; that it was unsafe to purchase certain drugs from NECC; that NECC was operating in violation of federal or state law; *etc.*).

FDA's investigation and inspection of, and action against NECC, following the meningitis outbreak

17. The findings of the FDA based on its investigation and inspection of NECC following the meningitis outbreak.

18. The source of the information contained in the NECC customer lists published by the FDA following the outbreak.

Documents

19. The documents that the witness(es) is requested to produce in the *duces tecum* attached as exhibit 1 to this Notice.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio
C.J. Gideon, Jr.*
Chris J. Tardio*
Alan S. Bean**
Matthew H. Cline*
315 Deaderick Street, Suite
Nashville, TN 37238
Ph: (615) 254-0400
Fax: (515) 254-0459
chris@gideoncooper.com

Attorneys for the Tennessee Clinic Defendants

* Admitted pursuant to MDL Order No. 1.
** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 6th day of March, 2015.

/s/ Chris J. Tardio
Chris J. Tardio

EXHIBIT 1

Duces Tecum to Notice

EXHIBIT 1 – *DUCES TECUM*

1. The witness's most current professional resume or *curriculum vitae*.

2. Any and all documents, including internal memoranda, internal communications, and external communications, related to FDA's investigation, inspection, and regulation of, and enforcement action against, NECC prior to the meningitis outbreak.

   Further instructions:

   > *To the extent these documents have already been produced to the Tennessee Clinic Defendants in response to the previous FOIA request, please simply confirm this.*
   >
   > *To the extent these documents have been posted on a website for public access (*e.g., *the FDA FOIA "reading room"), please identify the specific website where the Tennessee Clinic Defendants can access the entirety of the documents.*
   >
   > *If some documents are withheld on assertion of privilege or for any other reason, please identify the documents with reasonable particularity and the reason the documents have been withheld.*

3. All treatises, scholarly journals, professional studies, professional literature, or similar documents the witness intends to rely upon in giving testimony responsive to this Notice.

4. Any and all documents, not privileged, reviewed or relied on by the witness in preparation for giving testimony pursuant to the Notice.

5. FDA's internal policies, procedures, or training materials in place from 2002 to the time of the meningitis outbreak related to (1) the investigation, inspection, and regulation of, and enforcement action against, large-scale compounding pharmacies (compounding pharmacies operating beyond the definition of traditional compounding and acting more similar to conventional drug manufacturers) or (2) how FDA defined a traditional compounding pharmacy versus a large-scale compounding pharmacy acting more similar to a conventional drug manufacturer.

6. Any and all of NECC's documents, photographs, film, video, or exhibits obtained by the FDA in response to the meningitis outbreak.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 13-2419-RWZ
This Document Relates To:	
All Actions	

MDL Order No. 10
DEPOSITION PROTOCOL

September 18, 2014

Boal, M.J.

This Deposition Protocol shall govern cases transferred to this Court by the Judicial Panel on Multidistrict Litigation pursuant to its order of February 12, 2013, entitled New England Compounding Pharmacy, Inc. Products Liability Litigation, any tag-along actions transferred by the Panel after that date, and any related actions previously assigned to this Court. This Deposition Protocol is limited in scope to the discovery issues addressed herein. Additional discovery issues may need to be addressed in subsequent orders. For purposes of this Deposition Protocol, depositions of "Common Witnesses" and depositions on "Common Issues" shall refer to depositions of fact witnesses with knowledge of issues that pertain to all or a substantial number of cases in the Multidistrict Litigation ("MDL"), as opposed to depositions of witnesses with knowledge on issues pertaining to a single case or a small number of cases.

Should this Deposition Protocol need to be amended or additional provisions included to address issues with case-specific discovery and expert discovery, the parties shall meet and

confer to amend or add to this protocol. If the parties cannot agree, they may submit any remaining disputes to the Court.

I. GENERAL PROVISIONS

A. Lead Deposition Counsel

For purposes of scheduling and coordinating depositions, the MDL Plaintiffs shall designate a Lead Deposition Counsel for all depositions. For each deposition or set of related depositions particular to a Defendant, to the extent possible, the Defendants shall designate Lead Deposition Counsel for purposes of scheduling and coordination of the deposition(s).[1] Plaintiff depositions, third-party depositions, and depositions of employees, representatives, and former employees of the Defendants in this MDL action, and matters related to the conduct of these depositions shall be coordinated, to the extent possible, by Lead Deposition Counsel for Plaintiffs and Lead Deposition Counsel for Defendants, or their designees. The name and contact information for any designee shall be promptly communicated to the other parties. Additionally, counsel for a particular deponent shall be included in coordination of the deposition of that deponent. Counsel should consult in advance with opposing counsel and counsel for proposed deponents in an effort to schedule depositions at mutually convenient times and locations. Nothing in the Deposition Protocol shall be construed to allow counsel for other parties or witnesses to participate in the preparation of a party witness already represented by counsel.

B. Deposition Notices

1. *Notice of Deposition Procedures.* A copy of this Order shall be attached to each notice of deposition and/or any non-party subpoena to testify at a deposition, issued or served in these MDL proceedings.

[1] Representation for purposes of taking and defending depositions is discussed in Section II(A).

2. *Contents of Notice.* Information shall be provided as required by Fed. R. Civ. P. 30. Each deposition notice shall include the name of each deponent and the date, time and place of the deposition. If the notice asks the deponent to produce documents or information, or if the witness may be asked about documents that may contain confidential information, the witness shall be provided with a copy of the Third Amended Protective Order (Docket No. 814, or any additional amendments made by the Court thereto) (the "Protective Order").

C. Scheduling

1. The parties and the Court desire to minimize the expense and inconvenience of this litigation. Accordingly, all depositions of fact and expert witnesses taken in this MDL will be treated as if cross-noticed and taken in each of the individual cases in this MDL and all actions prosecuted by counsel having made an appearance in the MDL. In no event shall witnesses be deposed on multiple occasions on the same subjects in connection with these MDL proceedings without leave of Court and for good cause shown.

2. Plaintiffs and Defendants' Lead Deposition Counsel shall attempt to establish by mutual agreement a schedule for depositions in this MDL that reflects a sequencing consistent with (a) the availability of documents from among those produced by the parties and third parties; (b) the objective of not subjecting any party to repeated depositions; (c) the need to preserve relevant testimony; and (d) the schedule established by this Court.

3. If a party decides to take a deposition before all of the documents have been produced, they do so at their own risk and will not be allowed to re-depose the witness simply because additional documents were produced after the deposition absent agreement of the parties or permission from the Court for good cause shown. Production of additional documents alone shall not constitute good cause.

D. Cooperation

Counsel are expected to cooperate with and be courteous to each other and deponents in both scheduling and conducting depositions.

E. Attendance

Unless otherwise ordered under Fed. R. Civ. P. 26 (c), and subject to the restrictions set forth below, depositions may be attended by counsel of record, members and employees of their firms, members of the Plaintiffs' Steering Committee ("PSC"), attorneys specially engaged by a party for purposes of the deposition, the parties or the representative of a party, court reporters, videographers, the deponent, and counsel for the deponent. Without agreement of the parties, no more than ten (10) Plaintiffs' counsel, including members of the PSC, may attend in person any deposition. Nothing in the Joint Deposition Protocol shall be construed to limit the ability of counsel for a defendant to attend a deposition. While the deponent is being examined about any material designated Confidential, persons to whom disclosure is not authorized under the Protective Order shall be excluded from the deposition, except that counsel for any Plaintiff or the deponent shall not be so excluded. Any portion of the deposition transcript containing documents or information subject to the Protective Order entered in this case shall be sealed in accordance with the terms of the Protective Order.

F. Fed. R. Civ. P. 30(b)(6) Deposition

A party noticing a deposition of an entity pursuant to Fed. R. Civ. P. 30(b)(6) shall provide a list of topics for the deposition with reasonable particularity at least thirty (30) days in advance of the deposition in order to allow time for the noticed party to object to any of the topics and for the identification and preparation of person(s) designated to testify on such noticed topics. The noticed party shall submit its objections, if any, within fourteen (14) days of the

receipt of the 30(b)(6) deposition notice. Counsel for the deponent and the PSC may waive the aforementioned 30-day notice period. A party or non-party asked to provide a designee pursuant to a Fed. R. Civ. P. 30(b)(6) deposition notice shall provide notice of the name(s) of the individual(s) to be produced for deposition at least 7 days prior to commencement of the deposition, setting forth the matters upon which each person will testify.

II. CONDUCT OF DEPOSITIONS

A. Examination

Except in depositions that have been cross-noticed in actions pending in state court and without reference to the participation of coordinating counsel from the state court actions, questioning should ordinarily be conducted by no more than two attorneys for all MDL plaintiffs. Lead Deposition Counsel for Plaintiffs may designate typically no more than two attorneys representing personal injury Plaintiffs to participate in the questioning during each deposition. As it relates to a deposition conducted under Rule 30(b)(6) only, Lead Deposition Counsel for Plaintiffs may designate additional counsel for specific subject areas, and Lead Deposition Counsel shall inform counsel for the deponent at least 5 days before such deposition whether additional counsel will cover specific subject areas previously noticed and the specific subject areas additional counsel will cover. Counsel should endeavor to avoid asking the same or repetitive questions.

Counsel for the Unaffiliated Defendants[2] shall endeavor to designate two attorneys (not including, where applicable, the Defendant deponent's counsel) to represent the Unaffiliated Defendants during each deposition and participate in the deposition on behalf of all Unaffiliated

[2] "Unaffiliated Defendants" refers to Defendants who are not affiliated with New England Compounding Pharmacy, Inc. ("NECC").

Defendants. However, given the disparate interests of all Unaffiliated Defendants, this may not be possible.

Counsel for the Deponent shall "defend" the deposition. An objection by one party reserves the objection for all parties. All objections, except those which would be waived if not made at the deposition, are preserved and need not be made during the course of a deposition.

Each Deponent noticed during Common Issue phase discovery may only be deposed one time and his, her or its deposition applies to all cases pending in this MDL. Additional Plaintiffs and/or their counsel in this MDL may not re-notice or take the deposition of any Common Issue phase witness who has already testified except upon a showing before the Court of good cause and consistent with the Federal Rules of Civil Procedure.

B. Documents Used in Connection with Deposition.

1. *Marking of Deposition Exhibits.* All documents previously produced in the course of this litigation and used as exhibits with witnesses from a particular Defendant or non-party witness shall be referred to by the Bates stamp numbers appearing on the documents submitted to the document repositories. Documents that have not been previously produced in the course of this litigation shall be assigned a Bates stamp number from a range of numbers reserved for this purpose. The first time such a document is introduced as an exhibit at a deposition, it shall be marked with the assigned Bates stamp number and shall be produced at the conclusion of the deposition. Any documents marked as Exhibits during depositions shall be marked consecutively, (i.e. "Plaintiff Exhibit 1"), through the discovery phase such that if the first deposition ends with exhibit 11, then the first exhibit to the second deposition will start with exhibit 12. Whenever possible, previously marked exhibits should be used in subsequent depositions, rather than using a new exhibit number for the same exhibit.

2. The party who notices a deposition and/or the selected attorneys who will handle the examination shall strive to bring at least seven (7) copies of all non-introduced exhibits anticipated to be used for the deposition. It is understood that there will be certain instances (such as follow-up or to respond to the deponent's testimony) when the examining attorney(s) may need to introduce an exhibit that he or she did not anticipate and therefore may not have multiple copies available, and failure to bring the relevant copies shall not act as a bar to the introduction of such exhibit.

C. Limits on Duration and Number of Depositions

1. Absent permission from the Court or agreement of the parties, depositions shall be limited to one (1) day of seven (7) hours pursuant to Fed. R. Civ. P. 30(d)(1). Depositions should not typically begin before 9:00 a.m. and should typically conclude by 5:30 p.m. in the local time zone.

2. The PSC and each Defendant shall meet and confer to discuss a limit to the number of Common Witness depositions from that Defendant's employees, agents, former employees, and/or former agents. If the parties cannot agree on a limit, the Defendant may move for a protective order.

D. Location for Depositions

Defense counsel will make reasonable efforts to seek agreement of former employees of defendants to appear at designated locations. Absent such agreement, depositions will take place either within the federal district in which the former employee resides or at a location mutually agreeable to the former employee and the parties.

E. Coordination with State Court Actions, Cross-Noticing and Avoidance of Duplicative Depositions

1. *Coordination with State Court Actions.* In order to avoid duplicative discovery, minimize the number of times that a witness shall appear for a deposition, and to prevent the unnecessary expenditure of judicial resources and the resources of parties, counsel for Plaintiffs in the MDL shall use their best efforts to coordinate the scheduling of depositions with counsel for state court Plaintiffs. The Court expects that counsel for parties in the MDL proceeding will help ensure that such coordination is achieved where it is practicable.

2. *Cross-Noticing.* Any deposition in this MDL may be cross-noticed by any party in any clinic-related action pending in state court, and any deposition in any clinic-related action pending in state court may be cross-noticed by any party in this MDL. Each deposition notice shall include the information described in section I.B.2., supra. If a state court deposition has been cross-noticed in this MDL, then state court Plaintiffs represented by counsel with actions filed in this MDL may not take a subsequent deposition of that witness except for good cause shown as determined by the judge presiding over the proceeding in which the deposition is sought. In that case, any subsequent deposition shall be restricted to such additional inquiry permitted by the judge presiding over the proceeding in which the deposition is sought.

3. Nothing in Section III.F.1-2 shall be construed as an injunctive or equitable order affecting state court proceedings. Rather this provision is intended to reflect this Court's desire for voluntary state-federal coordination among the litigants and their counsel.

4. Unless it is jointly noticed by Plaintiffs in both the class action and personal injury matters, the noticing of a deposition by Plaintiffs' counsel for personal injury matters shall not count against the limitation on numbers of deposition prescribed under the Federal Rules of Civil Procedure for plaintiffs in any consolidated class action, and vice versa.

F. Early Depositions

If the parties become aware of any person who possess relevant information but, who, by reason of age, ill health, or termination of employment with defendants may become unavailable for deposition, the deposition may be taken as soon as possible, using the procedures outlined in Fed. R. Civ. P. 27.

G. Telephonic Depositions and Participation

The parties shall comply with Fed. R. Civ. P. 30(b)(4) regarding remote depositions. Non-examining counsel may attend depositions telephonically but are not permitted to participate absent extenuating circumstances, such as weather delay or physical restriction on travel or by agreement of counsel for the deponent.

H. Disputes During Depositions

If a dispute arises during a deposition that cannot be resolved by agreement, the deposition shall continue to be taken as to matters not in dispute. The parties shall present the dispute to the Court by motion at the earliest practicable time. Nothing in this Order shall deny counsel the right to suspend a deposition pursuant to Fed. R. Civ. P. 30(d)(3).

I. Video Depositions

After so indicating in its notice of a deposition, a party may, at its expense, record a deposition by videotape or digitally-recorded video pursuant to Fed. R. Civ. P. 30(b)(3) subject to the following rules:

1. *Video Operator.* The operator(s) of the video recording equipment shall be subject to the provisions of Fed. R. Civ. P. 28(c) and/or any protective order issued in the case pertaining to the deposition. At the commencement of the deposition, the operator(s) shall swear or affirm to record the proceedings fairly and accurately.

2. *Attendance*. Each witness, attorney and other person attending the deposition shall be identified on the record at the commencement of the deposition.

3. *Interruptions*. No attorney or party shall direct instructions to the video operator as to the method of operating the equipment. The video camera operation will be suspended during the deposition only upon agreement of counsel.

J. Correcting and Signing Deposition Transcripts

Unless waived by the deponent, the transcript of a deposition shall be submitted to the deponent within thirty (30) days after the end of the deposition for correction and signature. Upon receipt of the transcript, the deponent thereafter shall have thirty (30) days to make any corrections to the transcript, sign it, and return the transcript to the deposing party. If represented by counsel, a deponent need not sign any corrected transcript before a notary. If no corrections are made during this time, the transcript will be presumed accurate.

III. USE OF DEPOSITIONS

Depositions conducted in this MDL may be used in related cases in any state court to the extent permitted by that state's laws and rules. Depositions may be used by or against any party as permitted by the Federal Rules of Civil Procedure and the Federal Rules of Evidence.

IV. FEDERAL RULES OF CIVIL PROCEDURE APPLICABLE

Unless specifically modified herein, nothing in this Deposition Protocol shall be construed to abrogate the Federal Rules of Civil Procedure, including the right of any party or non-party to object to or seek a protective order to prevent the deposition of any witness.

So Ordered.

/s/ Jennifer C. Boal
JENNIFER C. BOAL
UNITED STATES MAGISTRATE JUDGE